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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,518	08/24/2001	Mark J. Jaroszeski	1372.34	2429
21901	7590	09/02/2008	EXAMINER	
SMITH HOPEN, PA 180 PINE AVENUE NORTH OLDSMAR, FL 34677			ANGELL, JON E	
			ART UNIT	PAPER NUMBER
			1635	
			MAIL DATE	DELIVERY MODE
			09/02/2008	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MARK J. JAROSZESKI, RICHARD GILBERT, and
RICHARD HELLER

Appeal 2008-4222
Application 09/939,518
Technology Center 1600

Decided: September 2, 2008

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and JEFFREY
N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of using electric fields to facilitate entry of molecules into cells, which the Examiner has rejected as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

BACKGROUND

“Most therapeutic molecules require delivery to a living cell by some means in order to effect a response” (Spec. 1). The Specification notes that “the cell membrane can partially or completely block the uptake of [therapeutic] molecule[s] into the cell itself. To overcome this, many methods have been developed; one such method is the use of electric fields to facilitate passage of the molecules from the extracellular space to the intracellular space” (Spec. 1). According to the Specification, “loading of molecules by electroporation *in vivo* is . . . carried out by first exposing the cells (located within a tissue) of interest to the molecule to be loaded. . . . The cells are then exposed to electric fields by administering one or more direct current pulses” (Spec. 2).

STATEMENT OF THE CASE

The Claims

Claims 1, 2, 6, 8, 10, 21, 22, and 24-28 are on appeal. We will focus on claim 1 which is representative and reads as follows:

1. A method for facilitating the delivery of a desired molecule into a target tissue consisting essentially of the steps of:
 - introducing a molecule into a target tissue comprising a cell;
 - applying an electric field to the target tissue, the application of the electric field consisting of a single continuous electric field in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes; and
 - effecting a change in porosity of the cell of the target tissue in response to the application of the electric field, the change in porosity sufficient to facilitate entry of a desired molecule into an interior of the cell.

The Issues

The Examiner relies upon the following prior art reference to show unpatentability:

Dimmer US 6,678,558 B1 Jan. 13, 2004

The rejection as presented by the Examiner is as follows:

Claims 1, 2, 6, 8, 10, 21, 22, and 24-28 stand rejected under 35 U.S.C. § 102(e), as being anticipated by Dimmer.

35 U.S.C. § 102(e) rejection over Dimmer

The Examiner argues that

Dimmer teaches a method for facilitating the delivery of a desired molecule into a target tissue consisting essentially of introducing a molecule into a target tissue comprising a cell, applying an electric field to the target tissue wherein the application of the electric field consists of a single continuous electric field including a plurality of substantially continuous electric fields in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes.

(Ans. 4.)

The Examiner specifically contends that “upon close examination of the instant claims, the ‘continuous electric field’ of the claims is NOT limited to a single pulse; rather, the ‘continuous electric field’ can comprise multiple electric pulses” (Ans. 8). The Examiner notes that it is only the “‘continuous electric field’ that must have a duration of 200ms to 20 minutes” (Ans. 8-9).

Appellants argue that “[o]ne would not equate a ‘continuous electric field’ or ‘pulse’ with Dimmer's ‘total electroporation signal duration’ or his

‘therapeutic signal’ as each of these can include items such as multiple pulses” (App. Br. 17). Appellants contend that “Dimmer does not expressly teach applying a continuous electric field in the range of 1mV/cm to 200V/cm to the target tissue for a duration of 200 ms” (Reply Br. 5). Appellants submit that “the phrase ‘continuous electric field’ is not anticipated by a teaching of a plurality of pulses” (Reply Br. 17).

In view of these conflicting positions, we frame the issue before us as follows:

Does Dimmer anticipate a method of electroporation in which a “continuous electric field” is applied for a duration of 200ms to 20 minutes as required by claims 1 and 21?

Findings of Fact

1. Claim 1 requires “application of the electric field consisting of a single continuous electric field in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes” (Claim 1).

2. The Specification teaches that the “concept of very long pulse durations (greater than 100 ms) has heretofore never been used with respect to field strength” (Spec. 3:10-11) for electroporation.

3. The Specification teaches that the prior art of Hoffman “describes electric field intensities ranging from 25 to 1300 V/cm with times or pulse widths ranging from 10 μ s to about 100 ms” (Spec. 3: 22-23).

4. The Specification teaches that one object of the invention is to provide a “method incorporating low electric fields and long pulse durations” (Spec. 4:12-13).

5. The Specification teaches that the “characteristics of the field used to facilitate the entry of the molecules into the target cell include field strengths between 1 mV/cm and 200 V/cm, applied as pulses of substantially continuous energy. The duration of the pulse ranges from 0.1 s to 20 minutes, with 100 ms to 100 s duration comprising a preferred range” (Spec. 6:6-9).

6. The Specification teaches that “the present inventors have discovered that by using a longer pulse duration, the field strength needed to effect facilitation of molecular delivery may be significantly lowered” (Spec. 6:13-15).

7. Dimmer teaches that a “therapeutic agent can be introduced to the treatment site before, after and/or during the passage of the therapeutic electrical signals between the electrodes. The therapeutic electrical signals can include an electroporation signal and/or an agent movement signal” (Dimmer, col. 5, ll. 5-9).

8. Dimmer teaches “[d]elivery of the electroporation signals preferably includes creating an energy field of at least about 25 V/cm and more preferably at least about 100 V/cm between two of the electrodes **16** of the electroporation therapy apparatus” (Dimmer, col. 10, ll. 29-32).

9. Dimmer teaches that the “total electroporation signal duration is preferably less than about 10 seconds, more preferably about 30 μ s-10 seconds, even more preferably about 30 μ s-1 ms and most preferably about 50 μ s-400 ms. When the electroporation signals include pulses, the total number of bipolar pulses is preferably 1 to 1,000,000” (Dimmer, col. 10, ll. 54-60).

10. Dimmer teaches that “[t]herapeutic electrical signals according to the present invention preferably have a pulse duration of less than about 50 μ s, more preferably have a pulse duration of less than about 12.5 μ s and most preferably a pulse duration of less than about 5 μ s” (Dimmer, col. 10, ll. 12-16).

11. Dimmer discloses that pulses alternate between periods of energy fields of zero volts and energy fields of the desired voltage (*see* Dimmer, fig. 5B).

12. The word “continuous” is defined as “uninterrupted: unbroken.”¹

13. The phrase “continuous wave” is defined as “emitting or capable of emitting continuously: not pulsed.”²

Discussion of the 35 U.S.C. § 102(e) rejection over Dimmer

We interpret the claims using the broadest reasonable interpretation. *See, e.g., In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000) (“[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification.”). In *Trans Texas Holdings*, the Federal Circuit provided a clear description of how to construe claims, noting

In *Phillips*, we held that while “the specification [should be used] to interpret the meaning of a claim,” courts must not “import[] limitations from the specification into the claim.” *Id.* at 1323. We specifically noted that it is improper to “confine the claims to th[e] embodiments” found in the specification, as *Trans Texas* asks us to do.

¹ Webster’s II New Riverside University Dictionary 305 (1984).

² *Id.*

In re Trans Texas Holdings Corp., 498 F.3d 1290, 1299 (Fed. Cir. 2007).

In the instant context, the question is the interpretation of the phrase “continuous electric field” in claim 1, and particularly the word “continuous”. While the Examiner correctly finds that Dimmer teaches electroporation using the claimed voltage, we find that three modes of claim interpretation militate against the interpretation of “continuous” as encompassing the pulsed electric fields of Dimmer (FF 7-11). Dimmer clearly teaches that the pulses should not exceed 50 μ s (FF 10) and Dimmer can only be interpreted as teaching a “continuous electric field” of 200 ms or greater duration if multiple pulses are applied (*see* Ans. 8, where the Examiner argues that “the ‘continuous electric field’ can comprise multiple electric pulses”).

First, construing the claim phrase “continuous electric field” in light of the Specification, we find that Appellants Specification repeatedly identifies the claimed invention as pulses of extended duration (FF 1, 2). Appellants’ Specification distinguishes prior art with pulses up to 100 ms (FF 3) but indicates that the invention is drawn to longer pulses (FF 4-6). The Specification notes that “characteristics of the field used to facilitate the entry of the molecules into the target cell include field strengths between 1 mV/cm and 200 V/cm, applied as pulses of substantially continuous energy. The duration of the pulse ranges from 0.1 s to 20 minutes, with 100 ms to 100 s duration comprising a preferred range” (Spec. 6:6-9). The statement “pulses of substantially continuous energy” in the Specification supports an interpretation of the phrase “single continuous electric field” in claim 1 as

excluding multiple electric pulses of Dimmer as argued by the Examiner (*see* Ans. 8).

Second, the Federal Circuit noted that “[u]nder *Phillips*, dictionary definitions are also pertinent. *See id.* at 1318 (‘[T]he court has observed that dictionaries ... can be useful in claim construction.’).” In re *Trans Texas Holdings*, 498 F.3d at 1299. Here, the dictionary definitions of “continuous” include “uninterrupted” and a definition of “continuous wave” is defined as “not pulsed” (FF 12, 13). We find that the proper interpretation requires reading “continuous” in the context both of its ordinary usage and its usage in electromagnetic waves, where the dictionary directly disagrees with the Examiner’s interpretation that something “continuous” can also be “pulsed” (*see* FF 13).

Third, the Dimmer reference itself indicates that pulses are not continuous, as shown by figures 4 and 5, where pulses show zero energy levels (FF 11). We are not persuaded by the Examiner's argument that a “‘continuous electric field’ can comprise multiple electric pulses” (Ans. 8). We find it unreasonable in light of the ordinary dictionary meaning of “continuous”, nor consistent with the instant Specification or Dimmer, to interpret something that is designated as “continuous” as encompassing multiple pulses in order to render the claims anticipated. The Federal Circuit addressed a similar question in *Buszard*, and noted “[w]e agree with Buszard that it is not a reasonable claim interpretation to equate ‘flexible’ with ‘rigid’” *In re Buszard*, 504 F.3d 1364, 1367 (Fed. Cir. 2007).

We agree with Appellants that “multiple electric pulses would involve a series of electric fields where the fields would be discontinuous between

each pulse” (Reply Br. 15). We also agree that while some claims “may be inelegantly worded” (Reply Br. 15), the broadest reasonable interpretation of a “continuous electric field” in claim 1 is that the time frame for the “continuous electric field” as reasonably interpreted represents a single pulse of between 200 ms to 20 minutes (Claim 1) and that the significantly shorter pulses disclosed by Dimmer do not anticipate (*see* FF 10).

We disagree with the Examiner that Dimmer teaches a single electric pulse of 200 ms (*see* Ans. 10). At no point does Dimmer teach a pulse of such length and Dimmer teaches “a pulse duration of less than about 50 μ s, more preferably have a pulse duration of less than about 12.5 μ s and most preferably a pulse duration of less than about 5 μ s” (Dimmer, col. 10, ll. 12-16). Dimmer’s claims support this conclusion, with claim 6 of dimmer claiming a range of pulse duration from 2 to 50 μ s (*see* Dimmer, col. 32, ll. 22-23, claim 6). While claim 4 of Dimmer teaches a method with as little as a single pulse, Dimmer never suggests that the length of the pulse should be more than 50 μ s, only that if there is a time delay between pulses, that time delay can be 5 to 200 ms (*see* Dimmer, col. 32, ll. 17-19, claim 4).

We are not persuaded by the Examiner’s citation of *In re Best*, 562 F.2d 1252 (CCPA 1977), in arguing that “administration of the ‘agent movement signal’ as described by Dimmer, would necessarily have the same result as the claimed method” (Ans. 5). This argument is irrelevant, since the claim is drawn to a specific method in which the “continuous electric field” is applied as at least one pulse with a duration of 200 ms to 20 minutes (*see* Claim 1). As we have concluded above, the short pulses of Dimmer do not anticipate the duration of the pulse required by claim 1. There is no

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requirement that the method result in improved or different results, only that the method is novel and unobvious. *See Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 1424 (Fed. Cir. 1988)(“Nothing in the patent statute requires that an invention be superior to the prior art to be patentable”).

We therefore reverse the rejection of claim 1 as anticipated by Dimmer. Having reversed the rejection of claim 1, we also reverse the rejections of the claims 2, 6, 8, 10, 21, 22, and 24-28 for the same reasons, because those claims also require a “continuous electric field”.

CONCLUSION

In summary, we reverse the rejection of claims 1, 2, 6, 8, 10, 21, 22, and 24-28 under 35 U.S.C. § 102(e).

REVERSED

cde

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